US008965471B2

(12) **United States Patent**
Lamego

(10) **Patent No.: US 8,965,471 B2**
(45) **Date of Patent: *Feb. 24, 2015**

(54) **TISSUE PROFILE WELLNESS MONITOR**

(71) Applicant: **Cercacor Laboratories, Inc.**, Irvine, CA (US)

(72) Inventor: **Marcelo Lamego**, Coto De Caza, CA (US)

(73) Assignee: **Cercacor Laboratories, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 68 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/764,007**

(22) Filed: **Feb. 11, 2013**

(65) **Prior Publication Data**

US 2013/0178749 A1 Jul. 11, 2013

Related U.S. Application Data

(63) Continuation of application No. 12/106,969, filed on Apr. 21, 2008, now Pat. No. 8,374,665.

(60) Provisional application No. 60/925,811, filed on Apr. 21, 2007.

(51) **Int. Cl.**

A61B 5/1455	(2006.01)
A61B 5/024	(2006.01)
A61B 5/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/02416*** (2013.01); ***A61B 5/7275*** (2013.01); ***A61B 5/14551*** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC .. A61B 5/0059; A61B 5/0075; A61B 5/1455; A61B 5/14551; A61B 5/75; A61B 5/7405; A61B 5/742; A61B 5/746; A61B 5/7271; A61B 5/7275

USPC 600/310, 322, 323, 324

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,910,701 A	10/1975	Henderson et al.
3,998,550 A	12/1976	Konishi et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0 231 379	8/1987
EP	41 92 23	3/1991

(Continued)

OTHER PUBLICATIONS

Burritt, Mary F.; Current Analytical Approaches to Measuring Blood Analytes; vol. 36; No. 8(B); 1990.

(Continued)

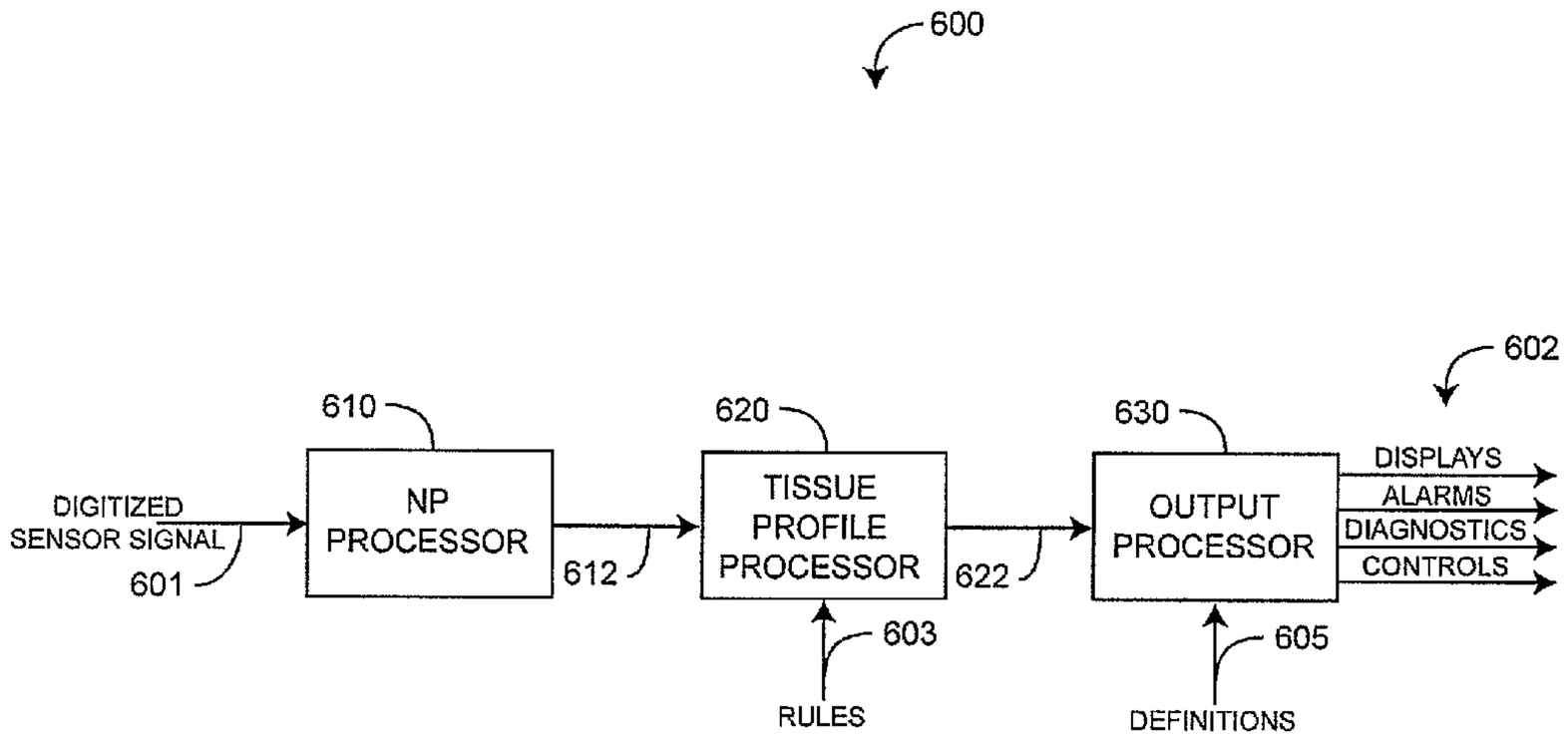
Primary Examiner — Eric Winakur

(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

A tissue profile wellness monitor measures a physiological parameter, generates a tissue profile, defines limits and indicates when the tissue profile exceeds the defined limits. The physiological parameter is responsive to multiple wavelengths of optical radiation after attenuation by constituents of pulsatile blood flowing within a tissue site. The tissue profile is responsive to the physiological parameter. The limits are defined for at least a portion of the tissue profile.

18 Claims, 5 Drawing Sheets



(52) **U.S. Cl.**
CPC ***A61B 5/72*** (2013.01); ***A61B 5/7405*** (2013.01); ***A61B 5/742*** (2013.01); ***A61B 5/746*** (2013.01); ***A61B 5/7475*** (2013.01)
USPC **600/322**; 600/324

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,014,321	A	3/1977	March
4,051,522	A	9/1977	Healy et al.
4,157,708	A	6/1979	Imura
4,167,331	A	9/1979	Nielsen
4,266,554	A	5/1981	Hamaguri
4,267,844	A	5/1981	Yamanishi
4,446,871	A	5/1984	Imura
4,531,527	A	7/1985	Reinhold, Jr. et al.
4,586,513	A	5/1986	Hamaguri
4,621,643	A	11/1986	New et al.
4,653,498	A	3/1987	New, Jr. et al.
4,655,225	A	4/1987	Dahne et al.
4,685,464	A	8/1987	Goldberger et al.
4,694,833	A	9/1987	Hamaguri
4,695,955	A	9/1987	Faisandier
4,700,708	A	10/1987	New et al.
4,714,341	A	12/1987	Hamaguri et al.
4,770,179	A	9/1988	New et al.
4,773,422	A	9/1988	Isaacson et al.
4,781,195	A	11/1988	Martin
4,800,885	A	1/1989	Johnson
4,805,623	A	2/1989	Jobsis
4,832,484	A	5/1989	Aoyagi et al.
4,846,183	A	7/1989	Martin
4,854,328	A	8/1989	Pollack
4,863,265	A	9/1989	Flower et al.
4,867,571	A	9/1989	Frick et al.
4,869,254	A	9/1989	Stone et al.
4,907,876	A	3/1990	Suzuki et al.
4,911,167	A	3/1990	Corenman et al.
4,934,372	A	6/1990	Corenman et al.
4,938,218	A	7/1990	Goodman et al.
4,942,877	A	7/1990	Sakai et al.
4,955,379	A	9/1990	Hall
4,960,126	A	10/1990	Conlon et al.
4,960,128	A	10/1990	Gordon et al.
4,964,010	A	10/1990	Miyasaka et al.
4,964,408	A	10/1990	Hink et al.
4,967,571	A	11/1990	Sporri
4,975,581	A	12/1990	Robinson et al.
4,986,665	A	1/1991	Yamanishi et al.
4,997,769	A	3/1991	Lundsgaard
5,025,791	A	6/1991	Niwa
RE33,643	E	7/1991	Isaacson et al.
5,028,787	A	7/1991	Rosenthal et al.
5,033,472	A	7/1991	Sato et al.
5,041,187	A	8/1991	Hink et al.
5,054,495	A	10/1991	Uemura et al.
5,058,588	A	10/1991	Kaestle
5,069,213	A	12/1991	Polczynski
5,077,476	A	12/1991	Rosenthal
5,078,136	A	1/1992	Stone et al.
5,101,825	A	4/1992	Gravenstein et al.
5,137,023	A	8/1992	Mendelson et al.
5,163,438	A	11/1992	Gordon et al.
5,188,108	A	2/1993	Secker
5,189,609	A	2/1993	Tivig et al.
5,190,040	A	3/1993	Aoyagi
5,209,230	A	5/1993	Swedlow et al.
5,226,053	A	7/1993	Cho et al.
5,246,002	A	9/1993	Prosser
5,247,931	A	9/1993	Norwood
5,259,381	A	11/1993	Cheung
5,267,562	A	12/1993	Ukawa et al.
5,267,563	A	12/1993	Swedlow et al.
5,278,627	A	1/1994	Aoyagi
5,297,548	A	3/1994	Pologe
5,313,940	A	5/1994	Fuse et al.
5,319,355	A	6/1994	Russek
5,331,549	A	7/1994	Crawford, Jr.
5,335,659	A	8/1994	Pologe et al.
5,337,744	A	8/1994	Branigan
5,337,745	A	8/1994	Benaron
5,341,805	A	8/1994	Stavridi et al.
5,348,004	A	9/1994	Hollub
5,351,685	A	10/1994	Potratz
5,355,880	A	10/1994	Thomas et al.
5,355,882	A	10/1994	Ukawa et al.
5,361,758	A	11/1994	Hall et al.
5,368,224	A	11/1994	Richardson et al.
D353,195	S	12/1994	Savage et al.
D353,196	S	12/1994	Savage et al.
5,372,136	A	12/1994	Steuer et al.
5,377,676	A	1/1995	Vari et al.
5,385,143	A	1/1995	Aoyagi
5,387,122	A	2/1995	Goldberger et al.
5,392,777	A	2/1995	Swedlow et al.
5,413,101	A	5/1995	Sugiura
D359,546	S	6/1995	Savage et al.
5,421,329	A	6/1995	Casciani et al.
5,424,545	A	6/1995	Block et al.
5,427,093	A	6/1995	Ogawa et al.
5,429,128	A	7/1995	Cadell et al.
5,431,170	A	7/1995	Mathews
5,435,309	A	7/1995	Thomas et al.
D361,840	S	8/1995	Savage et al.
D362,063	S	9/1995	Savage et al.
5,452,717	A	9/1995	Branigan et al.
D363,120	S	10/1995	Savage et al.
5,456,252	A	10/1995	Vari et al.
RE35,122	E	12/1995	Corenman et al.
5,479,934	A	1/1996	Imran
5,482,036	A	1/1996	Diab et al.
5,490,505	A	2/1996	Diab et al.
5,490,523	A	2/1996	Isaacson et al.
5,494,032	A	2/1996	Robinson et al.
5,494,043	A	2/1996	O'Sullivan et al.
5,503,148	A	4/1996	Pologe et al.
5,520,177	A	5/1996	Ogawa
5,533,507	A	7/1996	Potratz
5,533,511	A	7/1996	Kaspari et al.
5,534,851	A	7/1996	Russek
5,551,423	A	9/1996	Sugiura
5,553,615	A	9/1996	Carim et al.
5,555,882	A	9/1996	Richardson et al.
5,561,275	A	10/1996	Savage et al.
5,562,002	A	10/1996	Lalin
5,575,284	A	11/1996	Athan et al.
5,577,500	A	11/1996	Potratz
5,584,299	A	12/1996	Sakai et al.
5,588,427	A	12/1996	Tien
5,590,649	A	1/1997	Caro et al.
5,590,652	A	1/1997	Inai
5,595,176	A	1/1997	Yamaura
5,596,992	A	1/1997	Haaland et al.
5,602,924	A	2/1997	Durand et al.
5,603,623	A	2/1997	Nishikawa et al.
5,630,413	A	5/1997	Thomas et al.
5,632,272	A	5/1997	Diab et al.
5,638,816	A	6/1997	Kiani-Azarbayjany et al.
5,638,818	A	6/1997	Diab et al.
5,645,059	A	7/1997	Fein et al.
5,645,060	A	7/1997	Yorkey
5,645,440	A	7/1997	Tobler et al.
5,660,567	A	8/1997	Nierlich et al.
5,662,106	A	9/1997	Swedlow et al.
5,676,139	A	10/1997	Goldberger et al.
5,676,141	A	10/1997	Hollub
5,678,544	A	10/1997	DeLonzor et al.
5,685,299	A	11/1997	Diab et al.
5,685,301	A	11/1997	Klomhaus
5,687,719	A	11/1997	Sato et al.
5,687,722	A	11/1997	Tien et al.
5,690,104	A	11/1997	Kanemoto et al.
5,692,503	A	12/1997	Kuenstner
5,697,371	A	12/1997	Aoyagi et al.
5,713,355	A	2/1998	Richardson et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,719,589	A	2/1998	Norman et al.
5,720,284	A	2/1998	Aoyagi et al.
D393,830	S	4/1998	Tobler et al.
5,743,262	A	4/1998	Lepper, Jr. et al.
5,743,263	A	4/1998	Baker, Jr.
5,746,206	A	5/1998	Mannheimer
5,746,697	A	5/1998	Swedlow et al.
5,752,914	A	5/1998	Delonzor et al.
5,755,226	A	5/1998	Carim et al.
5,758,644	A	6/1998	Diab et al.
5,760,910	A	6/1998	Lepper, Jr. et al.
5,769,785	A	6/1998	Diab et al.
5,772,587	A	6/1998	Gratton et al.
5,779,630	A	7/1998	Fein et al.
5,782,237	A	7/1998	Casciani et al.
5,782,756	A	7/1998	Mannheimer
5,782,757	A	7/1998	Diab et al.
5,785,659	A	7/1998	Caro et al.
5,790,729	A	8/1998	Pologe et al.
5,791,347	A	8/1998	Flaherty et al.
5,792,052	A	8/1998	Isaacson et al.
5,793,485	A	8/1998	Gourley
5,800,348	A	9/1998	Kaestle
5,800,349	A	9/1998	Isaacson et al.
5,803,910	A	9/1998	Potratz
5,807,246	A	9/1998	Sakaguchi et al.
5,807,247	A	9/1998	Merchant et al.
5,810,723	A	9/1998	Aldrich
5,810,724	A	9/1998	Gronvall
5,810,734	A	9/1998	Caro et al.
5,817,010	A	10/1998	Hibl
5,818,985	A	10/1998	Merchant et al.
5,823,950	A	10/1998	Diab et al.
5,823,952	A	10/1998	Levinson et al.
5,827,182	A	10/1998	Raley et al.
5,830,131	A	11/1998	Caro et al.
5,830,137	A	11/1998	Scharf
5,833,618	A	11/1998	Caro et al.
5,839,439	A	11/1998	Nierlich et al.
RE36,000	E	12/1998	Swedlow et al.
5,842,979	A	12/1998	Jarman
5,851,178	A	12/1998	Aronow
5,851,179	A	12/1998	Ritson et al.
5,853,364	A	12/1998	Baker, Jr. et al.
5,857,462	A	1/1999	Thomas et al.
5,860,919	A	1/1999	Kiani-Azarbayjany et al.
5,865,736	A	2/1999	Baker, Jr. et al.
5,876,348	A	3/1999	Sugo
5,885,213	A	3/1999	Richardson et al.
5,890,929	A	4/1999	Mills et al.
5,891,022	A	4/1999	Pologe
5,891,024	A	4/1999	Jarman et al.
5,904,654	A	5/1999	Wohltmann et al.
5,910,108	A	6/1999	Solenberger
5,916,154	A	6/1999	Hobbs et al.
5,919,133	A	7/1999	Taylor
5,919,134	A	7/1999	Diab
5,921,921	A	7/1999	Potratz et al.
5,934,277	A	8/1999	Mortz
5,934,925	A	8/1999	Tobler et al.
5,940,182	A	8/1999	Lepper, Jr. et al.
5,954,644	A	9/1999	Dettling
5,978,691	A	11/1999	Mills
5,983,122	A	11/1999	Jarman et al.
5,995,855	A	11/1999	Kiani et al.
5,995,856	A	11/1999	Mannheimer et al.
5,995,859	A	11/1999	Takahashi
5,997,343	A	12/1999	Mills et al.
5,999,841	A	12/1999	Aoyagi et al.
6,002,952	A	12/1999	Diab et al.
6,006,119	A	12/1999	Soller et al.
6,011,986	A	1/2000	Diab et al.
6,014,576	A	1/2000	Raley
6,018,673	A	1/2000	Chin et al.
6,018,674	A	1/2000	Aronow
6,023,541	A	2/2000	Merchant et al.
6,027,452	A	2/2000	Flaherty et al.
6,036,642	A	3/2000	Diab et al.
6,045,509	A	4/2000	Caro et al.
6,064,898	A	5/2000	Aldrich
6,067,462	A	5/2000	Diab et al.
6,068,594	A	5/2000	Schloemer et al.
6,073,037	A	6/2000	Alam et al.
6,081,735	A	6/2000	Diab et al.
6,083,172	A	7/2000	Baker, Jr. et al.
6,088,607	A	7/2000	Diab et al.
6,094,592	A	7/2000	Yorkey et al.
6,104,938	A	8/2000	Huiku
6,110,522	A	8/2000	Lepper, Jr. et al.
6,112,107	A	8/2000	Hannula
6,122,042	A	9/2000	Wunderman et al.
6,124,597	A	9/2000	Shehada et al.
6,128,521	A	10/2000	Marro et al.
6,129,675	A	10/2000	Jay
6,144,868	A	11/2000	Parker
6,149,588	A	11/2000	Noda et al.
6,151,516	A	11/2000	Kiani-Azarbayjany et al.
6,151,518	A	11/2000	Hayashi
6,152,754	A	11/2000	Gerhardt et al.
6,154,667	A	11/2000	Miura et al.
6,157,041	A	12/2000	Thomas et al.
6,157,850	A	12/2000	Diab et al.
6,165,005	A	12/2000	Mills et al.
6,174,283	B1	1/2001	Nevo et al.
6,184,521	B1	2/2001	Coffin, IV et al.
6,192,261	B1	2/2001	Gratton et al.
6,206,830	B1	3/2001	Diab et al.
6,226,539	B1	5/2001	Potratz
6,229,856	B1	5/2001	Diab et al.
6,230,035	B1	5/2001	Aoyagi et al.
6,232,609	B1	5/2001	Snyder et al.
6,236,872	B1	5/2001	Diab et al.
6,241,683	B1	6/2001	Macklem et al.
6,248,083	B1	6/2001	Smith et al.
6,253,097	B1	6/2001	Aronow et al.
6,256,523	B1	7/2001	Diab et al.
6,262,698	B1	7/2001	Blum
6,263,222	B1	7/2001	Diab et al.
6,272,363	B1	8/2001	Casciani et al.
6,278,522	B1	8/2001	Lepper, Jr. et al.
6,280,213	B1	8/2001	Tobler et al.
6,285,895	B1	9/2001	Ristolainen et al.
6,285,896	B1	9/2001	Tobler et al.
6,298,252	B1	10/2001	Kovach et al.
6,301,493	B1	10/2001	Marro et al.
6,304,675	B1	10/2001	Osbourn et al.
6,304,767	B1	10/2001	Soller et al.
6,317,627	B1	11/2001	Ennen et al.
6,321,100	B1	11/2001	Parker
6,325,761	B1	12/2001	Jay
6,330,468	B1	12/2001	Scharf
6,334,065	B1	12/2001	Al-Ali et al.
6,341,257	B1	1/2002	Haaland
6,343,224	B1	1/2002	Parker
6,349,228	B1	2/2002	Kiani et al.
6,351,658	B1	2/2002	Middleman et al.
6,356,774	B1	3/2002	Bernstein et al.
6,360,113	B1	3/2002	Dettling
6,360,114	B1	3/2002	Diab et al.
6,363,269	B1	3/2002	Hanna et al.
6,368,283	B1	4/2002	Xu et al.
6,371,921	B1	4/2002	Caro et al.
6,374,129	B1	4/2002	Chin et al.
6,377,828	B1	4/2002	Chaiken et al.
6,377,829	B1	4/2002	Al-Ali
6,388,240	B2	5/2002	Schulz et al.
6,393,310	B1	5/2002	Kuenstner
6,397,091	B2	5/2002	Diab et al.
6,397,092	B1	5/2002	Norris et al.
6,397,093	B1	5/2002	Aldrich
6,408,198	B1	6/2002	Hanna et al.
6,411,833	B1	6/2002	Baker, Jr. et al.
6,415,166	B1	7/2002	Van Hoy et al.
6,415,233	B1	7/2002	Haaland

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,415,236	B2	7/2002	Kobayashi et al.	
6,421,549	B1	7/2002	Jacques	
6,430,437	B1	8/2002	Marro	
6,430,525	B1	8/2002	Weber et al.	
6,434,408	B1	8/2002	Heckel	
6,441,388	B1	8/2002	Thomas et al.	
6,453,184	B1	9/2002	Hyogo et al.	
6,455,340	B1	9/2002	Chua et al.	
6,463,310	B1	10/2002	Swedlow et al.	
6,463,311	B1	10/2002	Diab	
6,466,824	B1	10/2002	Struble	
6,470,199	B1	10/2002	Kopotic et al.	
6,480,729	B2	11/2002	Stone	
6,490,466	B1	12/2002	Chew et al.	
6,497,659	B1	12/2002	Rafert	
6,501,974	B2	12/2002	Huiku	
6,501,975	B2	12/2002	Diab et al.	
6,504,943	B1	1/2003	Sweatt et al.	
6,505,059	B1	1/2003	Kollias et al.	
6,505,060	B1	1/2003	Norris	
6,505,061	B2	1/2003	Larson	
6,505,133	B1	1/2003	Hanna	
6,510,329	B2	1/2003	Heckel	
6,515,273	B2	2/2003	Al-Ali	
6,519,486	B1	2/2003	Edgar, Jr. et al.	
6,519,487	B1	2/2003	Parker	
6,522,398	B2	2/2003	Cadell et al.	
6,525,386	B1	2/2003	Mills et al.	
6,526,300	B1	2/2003	Kiani et al.	
6,526,301	B2	2/2003	Larsen et al.	
6,528,809	B1	3/2003	Thomas et al.	
6,537,225	B1	3/2003	Mills	
6,541,756	B2	4/2003	Schulz et al.	
6,542,763	B1	4/2003	Yamashita et al.	
6,542,764	B1	4/2003	Al-Ali et al.	
6,545,652	B1	4/2003	Tsuji	
6,546,267	B1	4/2003	Sugiura	
6,553,241	B2	4/2003	Mannheimer et al.	
6,564,077	B2	5/2003	Mortara	
6,571,113	B1	5/2003	Fein et al.	
6,580,086	B1	6/2003	Schulz et al.	
6,582,964	B1	6/2003	Samsoondar et al.	
6,584,336	B1	6/2003	Ali et al.	
6,584,413	B1	6/2003	Keenan et al.	
6,591,123	B2	7/2003	Fein et al.	
6,594,511	B2	7/2003	Stone et al.	
6,594,518	B1 *	7/2003	Benaron et al.	600/342
6,595,316	B2	7/2003	Cybulski et al.	
6,597,932	B2	7/2003	Tian et al.	
6,597,933	B2	7/2003	Kiani et al.	
6,600,940	B1	7/2003	Fein et al.	
6,606,509	B2	8/2003	Schmitt	
6,606,510	B2	8/2003	Swedlow et al.	
6,606,511	B1	8/2003	Ali et al.	
6,609,016	B1	8/2003	Lynn	
6,611,698	B1	8/2003	Yamashita et al.	
6,614,521	B2	9/2003	Samsoondar et al.	
6,615,064	B1	9/2003	Aldrich	
6,615,151	B1	9/2003	Scecina et al.	
6,618,602	B2	9/2003	Levin	
6,622,095	B2	9/2003	Kobayashi et al.	
6,628,975	B1	9/2003	Fein et al.	
6,631,281	B1	10/2003	Kastle	
6,632,181	B2	10/2003	Flaherty et al.	
6,639,668	B1	10/2003	Trepagnier	
6,640,116	B2	10/2003	Diab	
6,643,530	B2	11/2003	Diab et al.	
6,650,917	B2	11/2003	Diab et al.	
6,654,623	B1	11/2003	Kastle	
6,654,624	B2	11/2003	Diab et al.	
6,657,717	B2	12/2003	Cadell et al.	
6,658,276	B2	12/2003	Pishney et al.	
6,658,277	B2	12/2003	Wasserman	
6,661,161	B1	12/2003	Lanzo et al.	
6,662,033	B2	12/2003	Casciani et al.	
6,665,551	B1	12/2003	Suzuki	
6,668,183	B2	12/2003	Hicks et al.	
6,671,526	B1	12/2003	Aoyagi et al.	
6,671,531	B2	12/2003	Al-Ali et al.	
6,675,031	B1	1/2004	Porges et al.	
6,675,106	B1	1/2004	Keenan et al.	
6,678,543	B2	1/2004	Diab et al.	
6,681,126	B2	1/2004	Solenberger	
6,684,090	B2	1/2004	Ali et al.	
6,684,091	B2	1/2004	Parker	
6,687,620	B1	2/2004	Haaland et al.	
6,690,466	B2	2/2004	Miller et al.	
6,694,157	B1	2/2004	Stone et al.	
6,697,655	B2	2/2004	Sueppel et al.	
6,697,656	B1	2/2004	Al-Ali	
6,697,657	B1	2/2004	Shehada et al.	
6,697,658	B2	2/2004	Al-Ali	
RE38,476	E	3/2004	Diab et al.	
6,699,194	B1	3/2004	Diab et al.	
6,701,170	B2	3/2004	Stetson	
6,708,049	B1	3/2004	Berson et al.	
6,711,503	B2	3/2004	Haaland	
6,714,803	B1	3/2004	Mortz	
6,714,804	B2	3/2004	Al-Ali et al.	
6,714,805	B2	3/2004	Jeon et al.	
RE38,492	E	4/2004	Diab et al.	
6,719,705	B2	4/2004	Mills	
6,720,734	B2	4/2004	Norris	
6,721,582	B2	4/2004	Trepagnier et al.	
6,721,584	B2	4/2004	Baker, Jr. et al.	
6,721,585	B1	4/2004	Parker	
6,725,074	B1	4/2004	Kastle	
6,725,075	B2	4/2004	Al-Ali	
6,726,634	B2	4/2004	Freeman	
6,728,560	B2	4/2004	Kollias et al.	
6,735,459	B2	5/2004	Parker	
6,741,875	B1	5/2004	Pawluczyk et al.	
6,741,876	B1	5/2004	Scecina et al.	
6,743,172	B1	6/2004	Blike	
6,745,060	B2	6/2004	Diab et al.	
6,745,061	B1	6/2004	Hicks et al.	
6,748,253	B2	6/2004	Norris et al.	
6,748,254	B2	6/2004	Chin et al.	
6,754,515	B1	6/2004	Pologe	
6,754,516	B2	6/2004	Mannheimer	
6,760,607	B2	7/2004	Al-All	
6,760,609	B2	7/2004	Jacques	
6,770,028	B1	8/2004	Ali et al.	
6,771,994	B2	8/2004	Kiani et al.	
6,773,397	B2	8/2004	Kelly	
6,778,923	B2	8/2004	Norris et al.	
6,780,158	B2	8/2004	Yarita	
6,788,849	B1	9/2004	Pawluczyk	
6,792,300	B1	9/2004	Diab et al.	
6,800,373	B2	10/2004	Gorczyca	
6,801,797	B2	10/2004	Mannheimer et al.	
6,801,799	B2	10/2004	Mendelson	
6,810,277	B2	10/2004	Edgar, Jr. et al.	
6,813,511	B2	11/2004	Diab et al.	
6,816,741	B2	11/2004	Diab	
6,819,950	B2	11/2004	Mills	
6,822,564	B2	11/2004	Al-Ali	
6,825,619	B2	11/2004	Norris	
6,826,419	B2	11/2004	Diab et al.	
6,829,496	B2	12/2004	Nagai et al.	
6,829,501	B2	12/2004	Nielsen et al.	
6,830,711	B2	12/2004	Mills et al.	
6,836,679	B2	12/2004	Baker, Jr. et al.	
6,839,579	B1	1/2005	Chin	
6,839,580	B2	1/2005	Zonios et al.	
6,839,582	B2	1/2005	Heckel	
6,842,702	B2	1/2005	Haaland et al.	
6,845,256	B2	1/2005	Chin et al.	
6,847,835	B1	1/2005	Yamanishi	
6,850,787	B2	2/2005	Weber et al.	
6,850,788	B2	2/2005	Al-Ali	
6,852,083	B2	2/2005	Caro et al.	
6,861,639	B2	3/2005	Al-Ali	
6,861,641	B1	3/2005	Adams	

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,869,402	B2	3/2005	Arnold
6,882,874	B2	4/2005	Huiku
6,898,452	B2	5/2005	Al-Ali et al.
6,912,049	B2	6/2005	Pawluczyk et al.
6,917,422	B2	7/2005	Samsoondar et al.
6,919,566	B1	7/2005	Cadell
6,920,345	B2	7/2005	Al-Ali et al.
6,921,367	B2	7/2005	Mills
6,922,645	B2	7/2005	Haaland et al.
6,928,311	B1	8/2005	Pawluczyk et al.
6,931,268	B1	8/2005	Kiani-Azarbayjany et al.
6,931,269	B2	8/2005	Terry
6,934,570	B2	8/2005	Kiani et al.
6,939,305	B2	9/2005	Flaherty et al.
6,943,348	B1	9/2005	Coffin, IV
6,944,487	B2	9/2005	Maynard et al.
6,950,687	B2	9/2005	Al-Ali
6,956,572	B2	10/2005	Zaleski
6,961,598	B2	11/2005	Diab
6,970,792	B1	11/2005	Diab
6,975,891	B2	12/2005	Pawluczyk
6,979,812	B2	12/2005	Al-Ali
6,985,764	B2	1/2006	Mason et al.
6,987,994	B1	1/2006	Mortz
6,993,371	B2	1/2006	Kiani et al.
6,996,427	B2	2/2006	Ali et al.
6,999,904	B2	2/2006	Weber et al.
7,001,337	B2	2/2006	Dekker
7,003,338	B2	2/2006	Weber et al.
7,003,339	B2	2/2006	Diab et al.
7,006,856	B2	2/2006	Baker, Jr. et al.
7,015,451	B2	3/2006	Dalke et al.
7,024,233	B2	4/2006	Ali et al.
7,027,849	B2	4/2006	Al-Ali
7,030,749	B2	4/2006	Al-Ali
7,039,449	B2	5/2006	Al-Ali
7,041,060	B2	5/2006	Flaherty et al.
7,044,918	B2	5/2006	Diab
7,067,893	B2	6/2006	Mills et al.
7,096,052	B2	8/2006	Mason et al.
7,096,054	B2	8/2006	Abdul-Hafiz et al.
7,132,641	B2	11/2006	Schulz et al.
7,142,901	B2	11/2006	Kiani et al.
7,149,561	B2	12/2006	Diab
7,186,966	B2	3/2007	Al-Ali
7,190,261	B2	3/2007	Al-Ali
7,215,984	B2	5/2007	Diab
7,215,986	B2	5/2007	Diab
7,221,971	B2	5/2007	Diab
7,225,006	B2	5/2007	Al-Ali et al.
7,225,007	B2	5/2007	Al-Ali et al.
RE39,672	E	6/2007	Shehada et al.
7,239,905	B2	7/2007	Kiani-Azarbayjany et al.
7,245,953	B1	7/2007	Parker
7,254,429	B2	8/2007	Schurman et al.
7,254,431	B2	8/2007	Al-Ali
7,254,433	B2	8/2007	Diab et al.
7,254,434	B2	8/2007	Schulz et al.
7,272,425	B2	9/2007	Al-Ali
7,274,955	B2	9/2007	Kiani et al.
D554,263	S	10/2007	Al-Ali et al.
7,280,858	B2	10/2007	Al-Ali et al.
7,289,835	B2	10/2007	Mansfield et al.
7,292,883	B2	11/2007	De Felice et al.
7,295,866	B2	11/2007	Al-Ali
7,299,080	B2	11/2007	Acosta et al.
7,328,053	B1	2/2008	Diab et al.
7,332,784	B2	2/2008	Mills et al.
7,340,287	B2	3/2008	Mason et al.
7,341,559	B2	3/2008	Schulz et al.
7,343,186	B2	3/2008	Lamego et al.
D566,282	S	4/2008	Al-Ali et al.
7,355,512	B1	4/2008	Al-Ali
7,356,365	B2	4/2008	Schurman
7,371,981	B2	5/2008	Abdul-Hafiz
7,373,193	B2	5/2008	Al-Ali et al.
7,373,194	B2	5/2008	Weber et al.
7,376,453	B1	5/2008	Diab et al.
7,377,794	B2	5/2008	Al-Ali et al.
7,377,899	B2	5/2008	Weber et al.
7,383,070	B2	6/2008	Diab et al.
7,415,297	B2	8/2008	Al-Ali et al.
7,428,432	B2	9/2008	Ali et al.
7,438,683	B2	10/2008	Al-Ali et al.
7,440,787	B2	10/2008	Diab
7,454,240	B2	11/2008	Diab et al.
7,467,002	B2	12/2008	Weber et al.
7,469,157	B2	12/2008	Diab et al.
7,471,969	B2	12/2008	Diab et al.
7,471,971	B2	12/2008	Diab et al.
7,483,729	B2	1/2009	Al-Ali et al.
7,483,730	B2	1/2009	Diab et al.
7,489,958	B2	2/2009	Diab et al.
7,496,391	B2	2/2009	Diab et al.
7,496,393	B2	2/2009	Diab et al.
D587,657	S	3/2009	Al-Ali et al.
7,499,741	B2	3/2009	Diab et al.
7,499,835	B2	3/2009	Weber et al.
7,500,950	B2	3/2009	Al-Ali et al.
7,509,154	B2	3/2009	Diab et al.
7,509,494	B2	3/2009	Al-Ali
7,510,849	B2	3/2009	Schurman et al.
7,526,328	B2	4/2009	Diab et al.
7,530,942	B1	5/2009	Diab
7,530,949	B2	5/2009	Al Ali et al.
7,530,955	B2	5/2009	Diab et al.
7,563,110	B2	7/2009	Al-Ali et al.
7,596,398	B2	9/2009	Al-Ali et al.
7,618,375	B2	11/2009	Flaherty et al.
D606,659	S	12/2009	Kiani et al.
7,647,083	B2	1/2010	Al-Ali et al.
D609,193	S	2/2010	Al-Ali et al.
7,670,726	B2	3/2010	Lu
D614,305	S	4/2010	Al-Ali et al.
RE41,317	E	5/2010	Parker
7,729,733	B2	6/2010	Al-Ali et al.
7,734,320	B2	6/2010	Al-Ali
7,761,127	B2	7/2010	Al-Ali et al.
7,761,128	B2	7/2010	Al-Ali et al.
7,764,982	B2	7/2010	Dalke et al.
D621,516	S	8/2010	Kiani et al.
7,791,155	B2	9/2010	Diab
7,801,581	B2	9/2010	Diab
7,822,452	B2	10/2010	Schurman et al.
RE41,912	E	11/2010	Parker
7,844,313	B2	11/2010	Kiani et al.
7,844,314	B2	11/2010	Al-Ali
7,844,315	B2	11/2010	Al-Ali
7,865,222	B2	1/2011	Weber et al.
7,873,497	B2	1/2011	Weber et al.
7,880,606	B2	2/2011	Al-Ali
7,880,626	B2	2/2011	Al-Ali et al.
7,891,355	B2	2/2011	Al-Ali et al.
7,894,868	B2	2/2011	Al-Ali et al.
7,899,507	B2	3/2011	Al-Ali et al.
7,899,518	B2	3/2011	Trepagnier et al.
7,904,132	B2	3/2011	Weber et al.
7,909,772	B2	3/2011	Popov et al.
7,910,875	B2	3/2011	Al-Ali
7,919,713	B2	4/2011	Al-Ali et al.
7,937,128	B2	5/2011	Al-Ali
7,937,129	B2	5/2011	Mason et al.
7,937,130	B2	5/2011	Diab et al.
7,941,199	B2	5/2011	Kiani
7,951,086	B2	5/2011	Flaherty et al.
7,957,780	B2	6/2011	Lamego et al.
7,962,188	B2	6/2011	Kiani et al.
7,962,190	B1	6/2011	Diab et al.
7,976,472	B2	7/2011	Kiani
7,988,637	B2	8/2011	Diab
7,990,382	B2	8/2011	Kiani
7,991,446	B2	8/2011	Ali et al.
8,000,761	B2	8/2011	Al-Ali
8,008,088	B2	8/2011	Bellott et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

RE42,753	E	9/2011	Kiani-Azarbayjany et al.
8,019,400	B2	9/2011	Diab et al.
8,028,701	B2	10/2011	Al-Ali et al.
8,029,765	B2	10/2011	Bellott et al.
8,036,728	B2	10/2011	Diab et al.
8,046,040	B2	10/2011	Ali et al.
8,046,041	B2	10/2011	Diab et al.
8,046,042	B2	10/2011	Diab et al.
8,048,040	B2	11/2011	Kiani
8,050,728	B2	11/2011	Al-Ali et al.
RE43,169	E	2/2012	Parker
8,118,620	B2	2/2012	Al-Ali et al.
8,126,528	B2	2/2012	Diab et al.
8,128,572	B2	3/2012	Diab et al.
8,130,105	B2	3/2012	Al-Ali et al.
8,145,287	B2	3/2012	Diab et al.
8,150,487	B2	4/2012	Diab et al.
8,175,672	B2	5/2012	Parker
8,180,420	B2	5/2012	Diab et al.
8,182,443	B1	5/2012	Kiani
8,185,180	B2	5/2012	Diab et al.
8,190,223	B2	5/2012	Al-Ali et al.
8,190,227	B2	5/2012	Diab et al.
8,203,438	B2	6/2012	Kiani et al.
8,203,704	B2	6/2012	Merritt et al.
8,224,411	B2	7/2012	Al-Ali et al.
8,228,181	B2	7/2012	Al-Ali
8,229,533	B2	7/2012	Diab et al.
8,233,955	B2	7/2012	Al-Ali et al.
8,244,325	B2	8/2012	Al-Ali et al.
8,255,026	B1	8/2012	Al-Ali
8,255,027	B2	8/2012	Al-Ali et al.
8,255,028	B2	8/2012	Al-Ali et al.
8,260,577	B2	9/2012	Weber et al.
8,265,723	B1	9/2012	McHale et al.
8,274,360	B2	9/2012	Sampath et al.
8,301,217	B2	10/2012	Al-Ali et al.
8,310,336	B2	11/2012	Muhsin et al.
8,315,683	B2	11/2012	Al-Ali et al.
RE43,860	E	12/2012	Parker
8,337,403	B2	12/2012	Al-Ali et al.
8,346,330	B2	1/2013	Lamego
8,353,842	B2	1/2013	Al-Ali et al.
8,355,766	B2	1/2013	MacNeish, III et al.
8,359,080	B2	1/2013	Diab et al.
8,364,223	B2	1/2013	Al-Ali et al.
8,364,226	B2	1/2013	Diab et al.
8,385,995	B2	2/2013	Al-Ali et al.
8,385,996	B2	2/2013	Smith et al.
8,388,353	B2	3/2013	Kiani et al.
8,399,822	B2	3/2013	Al-Ali
8,401,602	B2	3/2013	Kiani
8,405,608	B2	3/2013	Al-Ali et al.
8,414,499	B2	4/2013	Al-Ali et al.
8,418,524	B2	4/2013	Al-Ali
8,423,106	B2	4/2013	Lamego et al.
8,428,967	B2	4/2013	Olsen et al.
8,430,817	B1	4/2013	Al-Ali et al.
8,437,825	B2	5/2013	Dalvi et al.
8,455,290	B2	6/2013	Siskavich
8,457,703	B2	6/2013	Al-Ali
8,457,707	B2	6/2013	Kiani
8,463,349	B2	6/2013	Diab et al.
8,466,286	B2	6/2013	Bellott et al.
8,471,713	B2	6/2013	Poeze et al.
8,473,020	B2	6/2013	Kiani et al.
8,483,787	B2	7/2013	Al-Ali et al.
8,489,364	B2	7/2013	Weber et al.
8,498,684	B2	7/2013	Weber et al.
8,509,867	B2	8/2013	Workman et al.
8,515,509	B2	8/2013	Bruinsma et al.
8,523,781	B2	9/2013	Al-Ali
8,529,301	B2	9/2013	Al-Ali et al.
8,532,727	B2	9/2013	Ali et al.
8,532,728	B2	9/2013	Diab et al.
D692,145	S	10/2013	Al-Ali et al.
8,547,209	B2	10/2013	Kiani et al.
8,548,548	B2	10/2013	Al-Ali
8,548,550	B2	10/2013	Al-Ali et al.
8,560,032	B2	10/2013	Al-Ali et al.
8,560,034	B1	10/2013	Diab et al.
8,626,255	B2	1/2014	Al-Ali et al.
8,634,889	B2	1/2014	Al-Ali et al.
8,718,735	B2	5/2014	Lamego et al.
8,781,544	B2	7/2014	Al-Ali et al.
2001/0044700	A1	11/2001	Kobayashi et al.
2001/0045532	A1	11/2001	Schulz et al.
2002/0021269	A1	2/2002	Rast
2002/0026107	A1	2/2002	Kiani et al.
2002/0035315	A1	3/2002	Ali et al.
2002/0035318	A1	3/2002	Mannheimer et al.
2002/0038078	A1	3/2002	Ito
2002/0038081	A1	3/2002	Fein et al.
2002/0051290	A1	5/2002	Hannington
2002/0059047	A1	5/2002	Haaland
2002/0082488	A1	6/2002	Al-Ali et al.
2002/0095078	A1	7/2002	Mannheimer et al.
2002/0111748	A1	8/2002	Kobayashi et al.
2002/0115919	A1	8/2002	Al-Ali
2002/0154665	A1	10/2002	Funabashi et al.
2002/0156353	A1	10/2002	Larson
2002/0159002	A1	10/2002	Chang
2002/0161291	A1	10/2002	Kianl et al.
2002/0165440	A1	11/2002	Mason et al.
2002/0183819	A1	12/2002	Struble
2003/0045784	A1	3/2003	Palatnik et al.
2003/0045785	A1	3/2003	Diab et al.
2003/0049232	A1	3/2003	Page et al.
2003/0109775	A1	6/2003	O'Neil et al.
2003/0116769	A1	6/2003	Song et al.
2003/0117296	A1	6/2003	Seely
2003/0120160	A1	6/2003	Yarita
2003/0120164	A1	6/2003	Nielsen et al.
2003/0135099	A1	7/2003	Al-Ali
2003/0139657	A1	7/2003	Solenberger
2003/0160257	A1	8/2003	Bader et al.
2003/0195402	A1	10/2003	Fein et al.
2004/0006261	A1	1/2004	Swedlow et al.
2004/0033618	A1	2/2004	Haass et al.
2004/0034898	A1	2/2004	Bruegl
2004/0059209	A1	3/2004	Al-Ali et al.
2004/0064259	A1	4/2004	Haaland et al.
2004/0081621	A1	4/2004	Arndt et al.
2004/0092805	A1	5/2004	Yarita
2004/0133087	A1	7/2004	Ali et al.
2004/0138538	A1	7/2004	Stetson
2004/0138540	A1	7/2004	Baker, Jr. et al.
2004/0147822	A1	7/2004	Al-Ali et al.
2004/0147823	A1	7/2004	Kiani et al.
2004/0158132	A1	8/2004	Zaleski
2004/0158134	A1	8/2004	Diab et al.
2004/0158135	A1	8/2004	Baker, Jr. et al.
2004/0158162	A1	8/2004	Narimatsu
2004/0162472	A1	8/2004	Berson et al.
2004/0167382	A1	8/2004	Gardner et al.
2004/0171940	A1	9/2004	Narimatsu
2004/0176670	A1	9/2004	Takamura et al.
2004/0181134	A1	9/2004	Baker, Jr. et al.
2004/0199063	A1	10/2004	O'Neil et al.
2004/0204639	A1	10/2004	Casciani et al.
2004/0204868	A1	10/2004	Maynard et al.
2004/0229391	A1	11/2004	Ohya et al.
2004/0262046	A1	12/2004	Simond et al.
2004/0267103	A1	12/2004	Li et al.
2004/0267140	A1	12/2004	Ito et al.
2005/0011488	A1	1/2005	Doucet
2005/0033128	A1	2/2005	Ali et al.
2005/0043902	A1	2/2005	Haaland et al.
2005/0049469	A1	3/2005	Aoyagi et al.
2005/0054908	A1	3/2005	Blank et al.
2005/0070773	A1	3/2005	Chin et al.
2005/0070775	A1	3/2005	Chin et al.
2005/0075546	A1	4/2005	Samsoondar et al.
2005/0085704	A1	4/2005	Schulz et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0085735	A1	4/2005	Baker, Jr. et al.
2005/0124871	A1	6/2005	Bake, Jr. et al.
2005/0143634	A1	6/2005	Baker, Jr. et al.
2005/0143943	A1	6/2005	Brown
2005/0148834	A1	7/2005	Hull et al.
2005/0184895	A1	8/2005	Petersen et al.
2005/0187447	A1	8/2005	Chew et al.
2005/0187448	A1	8/2005	Petersen et al.
2005/0187449	A1	8/2005	Chew et al.
2005/0187450	A1	8/2005	Chew et al.
2005/0187452	A1	8/2005	Petersen et al.
2005/0187453	A1	8/2005	Petersen et al.
2005/0197549	A1	9/2005	Baker
2005/0197579	A1	9/2005	Baker
2005/0197793	A1	9/2005	Baker
2005/0203357	A1	9/2005	Debreczeny et al.
2005/0209515	A1	9/2005	Hockersmith et al.
2005/0228253	A1	10/2005	Debreczeny
2005/0250997	A1	11/2005	Takeda et al.
2006/0030764	A1	2/2006	Porges et al.
2006/0210120	A1	9/2006	Rowe et al.
2006/0211922	A1	9/2006	Al-Ali et al.
2006/0211923	A1	9/2006	Al-Ali et al.
2006/0211924	A1	9/2006	Dalke et al.
2006/0211925	A1	9/2006	Lamego et al.
2006/0211932	A1	9/2006	Al-Ali et al.
2006/0226992	A1	10/2006	Al-Ali et al.
2006/0229509	A1	10/2006	Al-Ali et al.
2006/0238358	A1	10/2006	Al-Ali et al.
2006/0241358	A1	10/2006	Al-Ali et al.
2006/0241363	A1	10/2006	Al-Ali et al.
2006/0264718	A1	11/2006	Ruchti et al.
2007/0149864	A1	6/2007	Laakkonen
2007/0185397	A1	8/2007	Govari et al.
2011/0009719	A1	1/2011	Al-Ali et al.
2011/0237914	A1	9/2011	Lamego et al.
2012/0046530	A1	2/2012	Al-Ali
2012/0161970	A1	6/2012	Al-Ali
2012/0232359	A1	9/2012	Al-Ali et al.
2012/0232363	A1	9/2012	Al-Ali et al.
2013/0172701	A1	7/2013	Smith et al.
2013/0178749	A1	7/2013	Lamego

FOREIGN PATENT DOCUMENTS

EP	0 569 670	2/1993
EP	0 529 412	3/1993
EP	0 675 540	10/1995
EP	0 675 541	10/1995
EP	1 080 683	3/2001
EP	1 207 536	5/2002
EP	1 860 989	12/2007
EP	1 895 892	5/2010
EP	2 286 721	2/2011
EP	2 305 104	4/2011
EP	2 476 369	7/2012
EP	2 139 383	2/2013
JP	61-28172	2/1986
JP	62-000324	1/1987
JP	63-275327	11/1988
JP	64-500495	2/1989
JP	2-126829	5/1990
JP	2-145457	12/1990
JP	05-200017	8/1993
JP	05-207993	8/1993
JP	6-505903	7/1994
JP	6-237013	8/1994
JP	7-281618	10/1995
JP	07-325546	12/1995
JP	9-192120	7/1997
JP	09-308623	12/1997
JP	10-500026	1/1998
JP	H10-500026	1/1998
JP	10-216112	8/1998
JP	10-509352	9/1998
JP	10-269344 A	10/1998
JP	10-295676	11/1998
JP	10-305026	11/1998
JP	11-037932	2/1999
JP	11-163412	6/1999
JP	11-164826	6/1999
JP	11-506834	6/1999
JP	11-183377	7/1999
JP	H11-508691	7/1999
JP	2000-116625	4/2000
JP	2002-516689	6/2002
JP	2002-228579	8/2002
JP	2002-525151	8/2002
JP	2002-315739	10/2002
JP	2003-507718	2/2003
JP	2003-084108	3/2003
JP	2003-521985	7/2003
JP	2004-070179	3/2004
JP	2004-510467	4/2004
JP	2004-173866	6/2004
JP	2004-226277	8/2004
JP	2004-296736	10/2004
JP	2004-532526	10/2004
JP	2004-327760	11/2004
JP	2005-501589	1/2005
JP	2005-253478	9/2005
JP	2008-505706	2/2008
JP	4865737	11/2011
JP	4879913	12/2011
JP	2012-110746	6/2012
JP	2012-130756	7/2012
JP	5096174	9/2012
JP	5166619	3/2013
JP	5456976	1/2014
WO	WO 88/01150	2/1988
WO	WO 88/02020	2/1988
WO	WO 92/16142	10/1992
WO	WO 95/16387	6/1995
WO	WO 96/13208	5/1996
WO	WO 96/41138	12/1996
WO	WO 97/01985	1/1997
WO	WO 98/43071	10/1998
WO	WO 00/18290	4/2000
WO	WO 00/42911	7/2000
WO	WO 00/59374	10/2000
WO	WO 01/13790	3/2001
WO	WO 01/30414	5/2001
WO	WO 01/58347	8/2001
WO	WO 02/17780	3/2002
WO	WO 02/26123	4/2002
WO	WO 02/089664	11/2002
WO	WO 03/020129	3/2003
WO	WO 03/068060	8/2003
WO	WO 03/077761	9/2003
WO	WO 2004/034898	4/2004
WO	WO 2004/038801	5/2004
WO	WO 2005/004712	1/2005
WO	WO 2005/011488	2/2005
WO	WO 2006/017117	2/2006
WO	WO 2006/094107	9/2006
WO	WO 2006/094168	9/2006
WO	WO 2009/137524	11/2009

OTHER PUBLICATIONS

European Extended Search Report, re EP Application No. 10191029.7, dated Jun. 5, 2012.

European Examination Report dated Apr. 1, 2010, re EP App. No. 08 744 412.1-2319.

European Examination Report dated Mar. 18, 2011, re EP App. No. 08 744 412.1-2319.

European Examination Report dated Sep. 2, 2010, re EP App. No. 08 744 412.1-2319.

European Examination Report, re EP Application No. 12163719.3, dated Feb. 6, 2013.

European Extended Search Report of European Application No. 12163719.3, mailing date of Jun. 18, 2012, in 6 pages.

(56) **References Cited**

OTHER PUBLICATIONS

European Extended Search Report re EPO App. No. 10162402.1, SR dated Aug. 9, 2010.
European Office Action re Ep Application No. 06 736 799.5, dated Nov. 30, 2012.
Hall, et al., Jeffrey W.; Near-Infrared Spectrophotometry: A New Dimension in Clinical Chemistry; vol. 38; No. 9; 1992.
International Preliminary Report on Patentability for PCT/US2010/058981 issued Jun. 5, 2012, mailed Jun. 14, 2012.
International Search Report for PCT/US2006/007516, mailed on Jan. 11, 2007.
Japanese Office Action (Notice of Reasons for Rejection) re JP App. No. 2007-558246, dated Jun. 28, 2011.
Japanese Office Action (Official Inquiry) re JP App. No. 2007-558246, dated Dec. 11, 2012.
Japanese Office Action (Reasons for Rejection) re JP App. No. 2007-558246, dated Nov. 1, 2011.
Japanese Office Action, re JP Application No. 2012-045419, dated Jun. 26, 2012.
Japanese Office Action re JP Application No. Jp 2007-558208, dated Aug. 23, 2011.
Japanese First Office Action (Notice of Reasons for Rejection), re JP App. No. 2007-558247, dated Jun. 28, 2011.
Japanese Office Action (Notice of Allowance), re JP App. No. 2007-558247, dated Oct. 24, 2011.
Japanese Office Action (Decision of Rejection), re JP Application No. JP 2007-558328, dated Jun. 25, 2013.
Japanese Office Action (Notice of Reasons for Rejection), re JP App. No. 2007-558238, dated Jun. 28, 2011.
Japanese Office Action (Official Inquiry), re JP App. No. 2007-558238/Appeal No. 2012-004053, dated Dec. 11, 2012.
Japanese Office Action re JP Application No. JP 2007-558248, dated Nov. 27, 2012.
Japanese Office Action re JP Application No. JP 2007-558248, dated Nov. 8, 2011.
Japanese First Office Action (Notice of Reasons for Rejection), re JP App. No. 2007-558207, dated Jun. 28, 2011.
Japanese Office Action, re JP Application No. 2007-558237, dated Aug. 2, 2011.
Japanese Office Action, re JP Application No. JP 2007-558237, mailed Oct. 16, 2012.
Japanese Office Action re JP Application No. 2007-558209, dated Oct. 25, 2011.
Japanese Office Action re JP Application No. 2007-558209, dated Oct. 30, 2012.
Japanese Office Action re JP Application No. 2007-558245, dated Oct. 25, 2011.
Japanese Office Action re JP Application No. 2007-558245, dated/mailed Jan. 15, 2013.
Japanese Office Action re JP Application No. 2007-558245, mailed Oct. 29, 2013.
Japanese Final Office Action re Amendments re JP Application No. 2007-558249, dated Apr. 17, 2012.
Japanese Office Action re JP Application No. 2007-558249, dated Aug. 28, 2012.
Japanese Office Action re JP Application No. 2007-558249, dated Jul. 13, 2011.
Japanese Office Action re JP Application No. 2007-558249, dated Nov. 8, 2011.
Kuenstner, et al., J. Todd; Measurement of Hemoglobin in Unlysed Blood by Near-Infrared Spectroscopy; vol. 48; No. 4, 1994.
Manzke, et al., B., Multi Wavelength Pulse Oximetry in the Measurement of Hemoglobin Fractions; vol. 2676, date unknown.
Naumenko, E. K.; Choice of Wavelengths for Stable Determination of Concentrations of Hemoglobin Derivatives from Absorption Spectra of Erythrocytes; vol. 63; No. 1; pp. 43-48 Jan.-Feb. 1996; Original article submitted Nov. 3, 1994.
PCT International Search Report; PCT/US2006/007537; Date of Mailing Jul. 17, 2006.
PCT International Search Report and Written Opinion; PCT/US2006/007388; Date of Mailing Jul. 17, 2006.
PCT International Search Report; PCT/US2006/007538; Date of Mailing Jul. 17, 2006.
PCT International Search Report; PCT/US2006/007958; Date of Mailing Jul. 17, 2006.
PCT International Search Report; PCT/US2006/007539; Date of Mailing Jul. 17, 2006.
PCT International Search Report and Written Opinion; PCT/US2006/007387; Date of Mailing Jul. 17, 2006.
PCT International Written Opinion and Search Report; PCT/US2006/007506, dated Jul. 17, 2006.
PCT International Search Report and Written Opinion; PCT/US 2006/007389; Date of Mailing Jul. 17, 2006.
PCT International Search Report; PCT/US2006/007536; Date of Mailing Jul. 17, 2006.
PCT International Search Report; PCT/US2006/007540; Date of Mailing Jul. 17, 2006.
PCT Preliminary Report on Patentability; PCT/US2008/058327, Mailing Date of Jun. 30, 2009.
Schmitt, Joseph M.; Simple Photon Diffusion Anaylsis of the Effects of Multiple Scattering on Pulse Oximetry; Mar. 14, 1991; revised Aug. 30, 1991.
Schmitt, Joseph M.; Zhou, Guan-Xiong; Miller, Justin, Measurement of Blood Hematocrit by Dual-wavelength Near-IR Photoplethysmography, published May 1992, Proc. SPIE vol. 1641, p. 150-161, Physiological Monitoring and Early Detection Diagnostic Methods, Thomas S. Mang; Ed. (SPIE homepage), in 12 pages.
Schnapp, et al., L.M.; Pulse Oximetry. Uses and Abuses.; Chest 1990; 98; 1244-125000110.1378/Chest.98.5.1244.

* cited by examiner

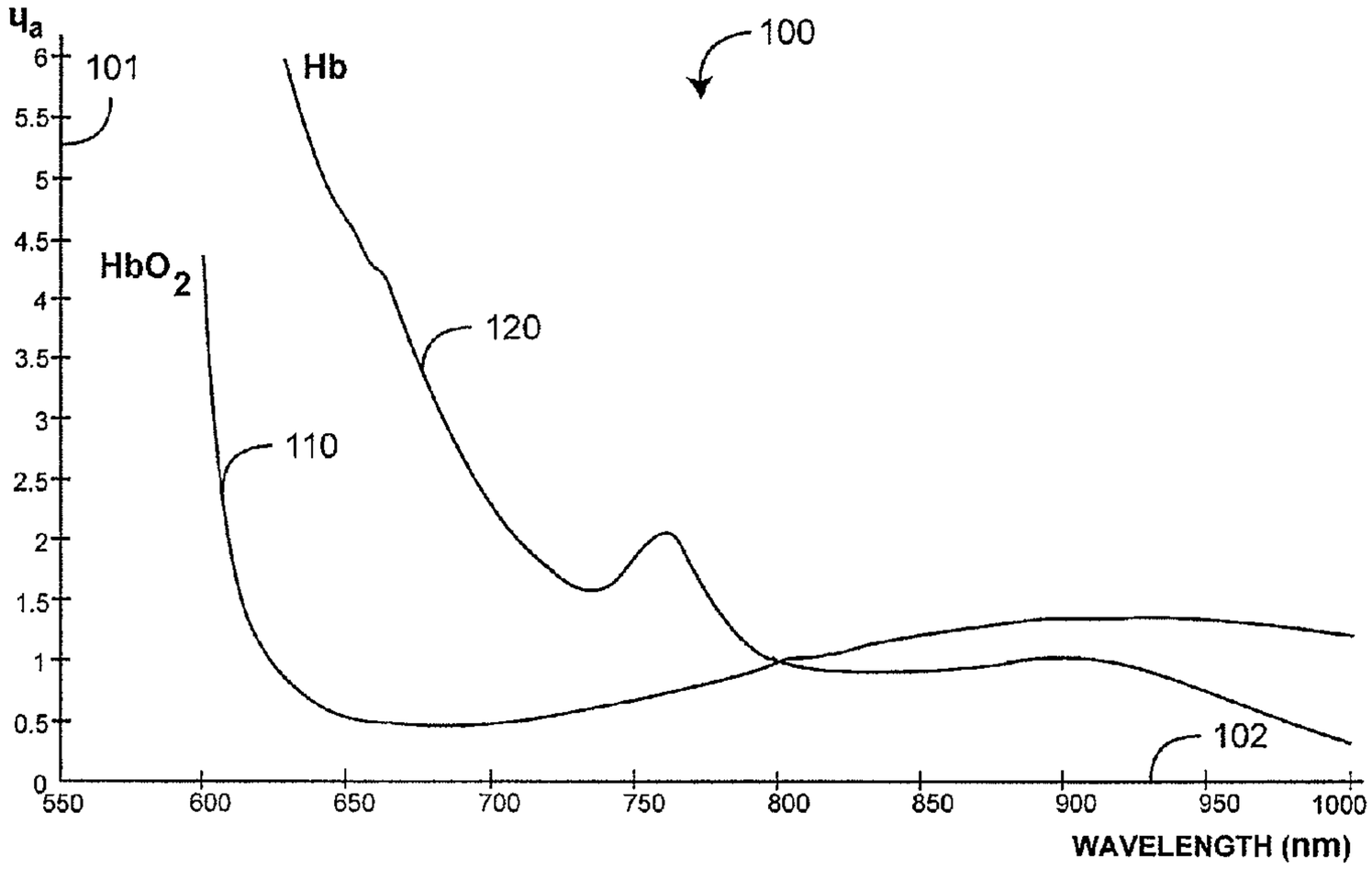

μ_a
6
5.5
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
101
Hb
HbO_2
100
120
110
102
550
600
650
700
750
800
850
900
950
1000
WAVELENGTH (nm)

FIG. 1

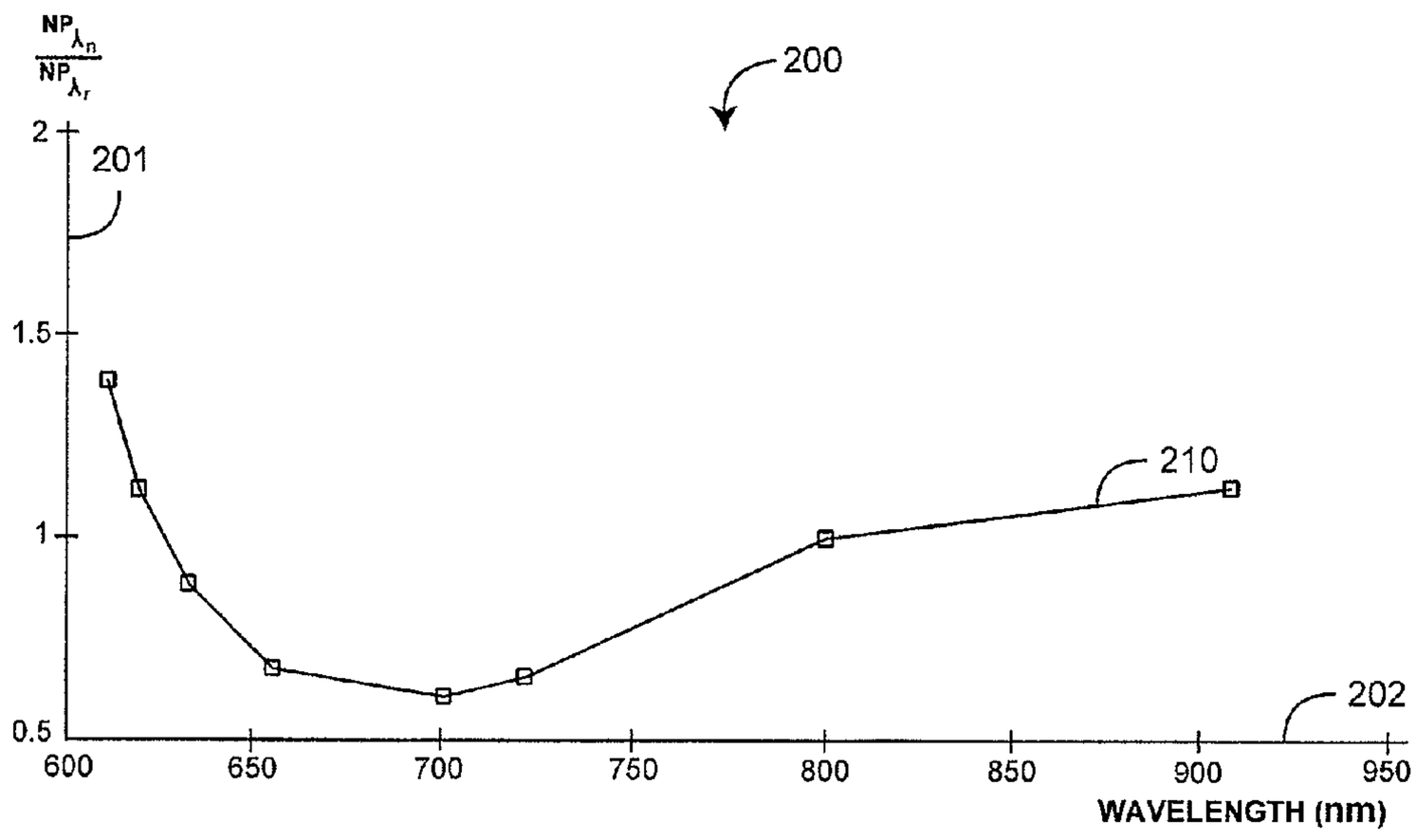

$\frac{NP_{\lambda_n}}{NP_{\lambda_r}}$
2
1.5
1
0.5
201
200
210
202
600
650
700
750
800
850
900
950
WAVELENGTH (nm)

FIG. 2

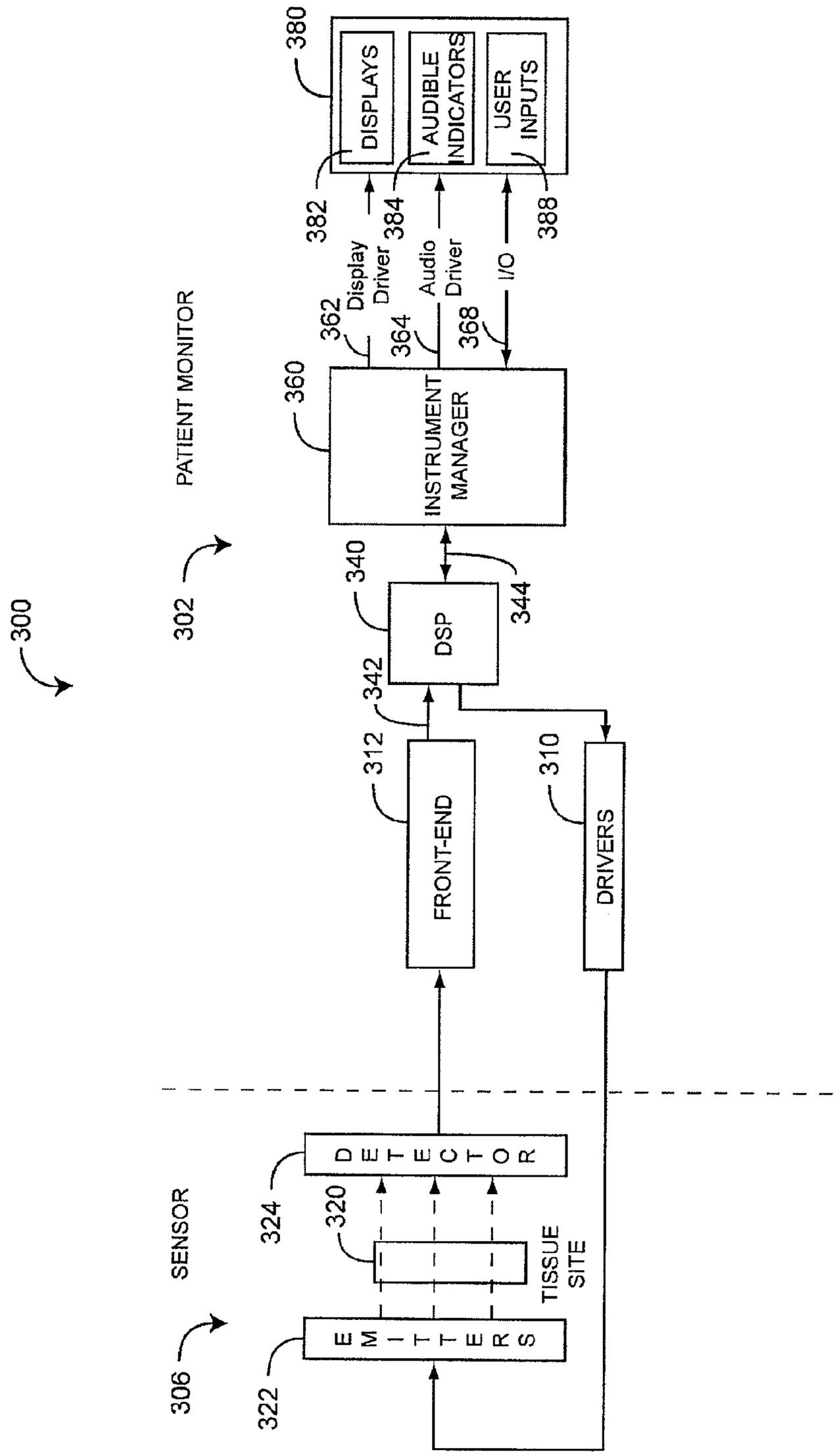

300
PATIENT MONITOR
302
380
DISPLAYS
AUDIBLE INDICATORS
USER INPUTS
382
384
388
Display Driver
Audio Driver
I/O
362
364
368
360
INSTRUMENT MANAGER
340
344
DSP
342
312
310
FRONT-END
DRIVERS
SENSOR
306
322
EMITTERS
324
320
DETECTOR
TISSUE SITE

FIG. 3

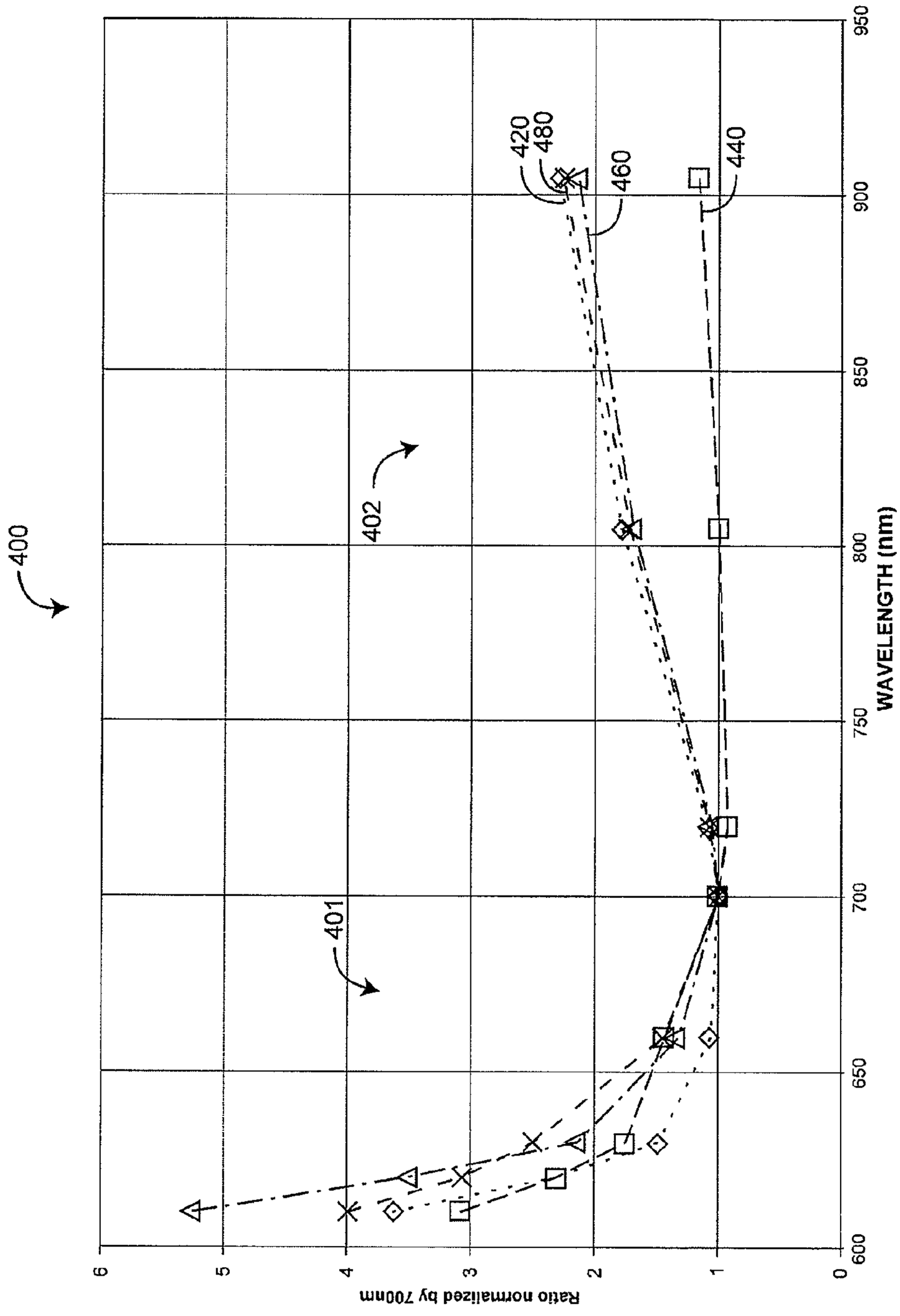

400
401
402
420
480
460
440
950
900
850
800
750
700
650
600
WAVELENGTH (nm)
0
1
2
3
4
5
6
Ratio normalized by 700nm

FIG. 4

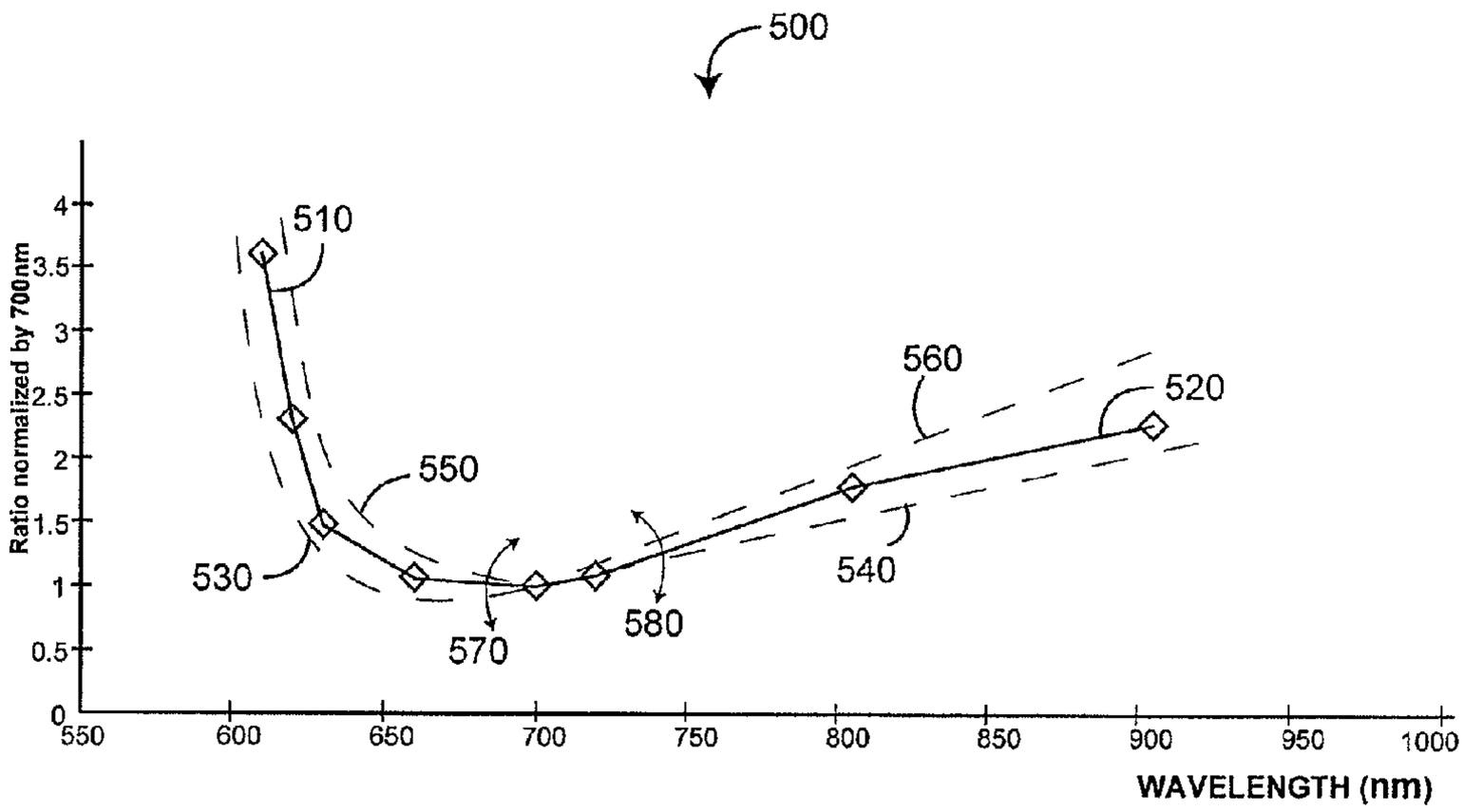

500
510
520
530
540
550
560
570
580
Ratio normalized by 700nm
WAVELENGTH (nm)
0
0.5
1
1.5
2
2.5
3
3.5
4
550
600
650
700
750
800
850
900
950
1000

FIG. 5

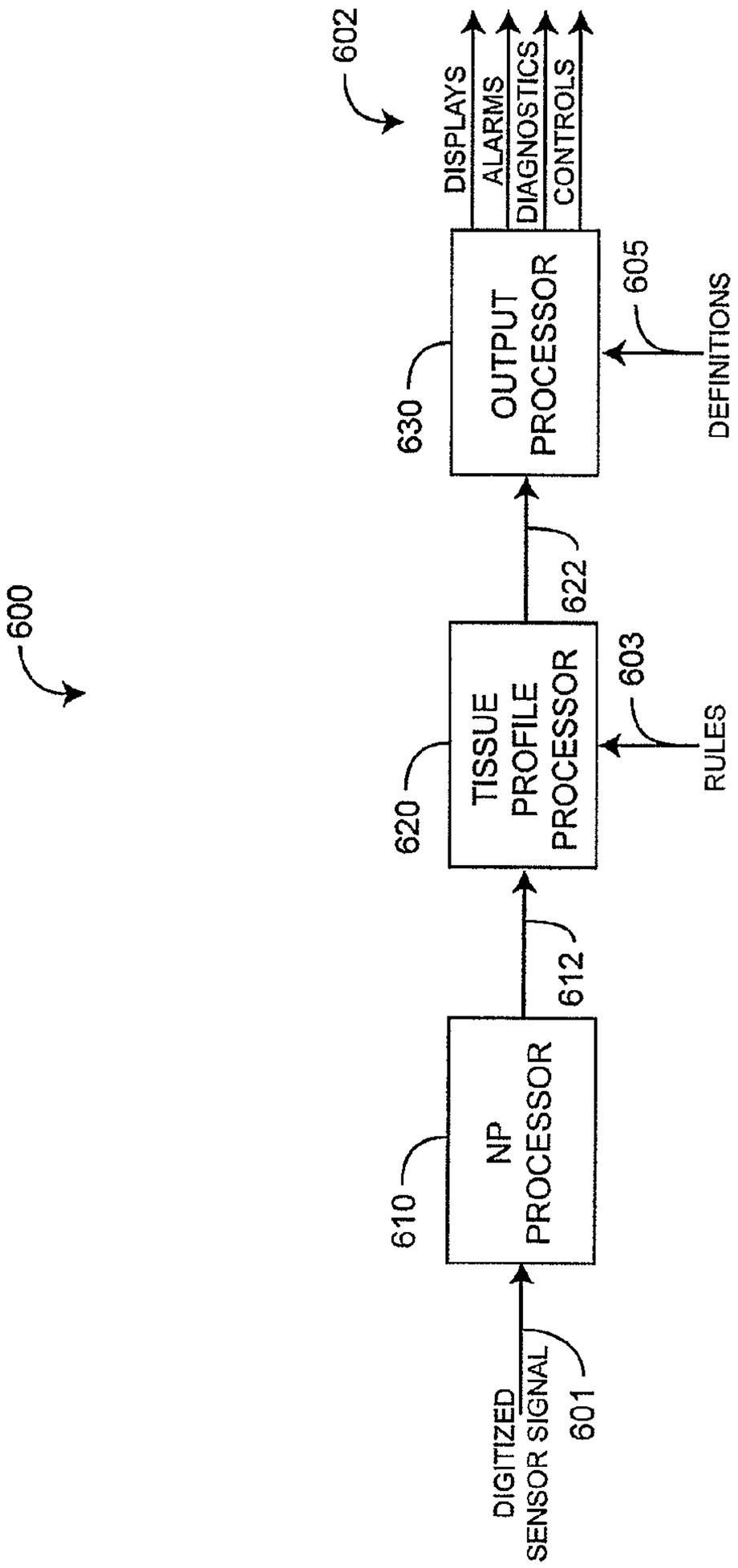

600
602
DISPLAYS
ALARMS
DIAGNOSTICS
CONTROLS
OUTPUT PROCESSOR
630
605
DEFINITIONS
TISSUE PROFILE PROCESSOR
620
603
RULES
622
612
NP PROCESSOR
610
DIGITIZED SENSOR SIGNAL
601

FIG. 6

TISSUE PROFILE WELLNESS MONITOR

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 12/106,969, filed Apr. 21, 2008, entitled "TISSUE PROFILE WELLNESS MONITOR," which claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Application Ser. No. 60/925,811, filed Apr. 21, 2007, entitled "TISSUE PROFILE WELLNESS MONITOR." All of the above referenced applications are hereby incorporated by reference in their entirety herein.

BACKGROUND OF THE INVENTION

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path length d_λ, the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

Where $\mu_{\alpha,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve EQS. 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation ($Sp0_2$) and pulse rate. The sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after attenuation by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for $Sp0_2$ and pulse rate, and outputs representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,584,336, 6,263,222, 6,157,850, 5,769,785, and 5,632,272, which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all type of monitoring scenarios.

FIG. **1** illustrates an absorption graph **100** having a dimensionless vertical axis **101** of relative light absorption and a horizontal axis **102** of transmitted wavelength in nm. Shown is a plot of $Hb0_2$ absorption **110** and Hb absorption **120** versus wavelength, both normalized to the absorption at 800 nm. At red and near IR wavelengths below 970 nm, where water has a significant peak, Hb and $Hb0_2$ are the only significant absorbers normally present in the blood. Thus, typically only two wavelengths are needed to resolve the concentrations of Hb and $Hb0_2$, e.g. a red (RD) wavelength at 660 nm and an infrared (IR) wavelength at 940 nm. In particular, $Sp0_2$ is computed based upon a red ratio Red_{AC}/Red_{DC} and an IR ratio IR_{AC}/IR_{DC}, which are the AC detector response magnitude at a particular wavelength normalized by the DC detector response at that wavelength. The normalization by the DC detector response reduces measurement sensitivity to variations in tissue thickness, emitter intensity and detector sensitivity, for example. The AC detector response is a plethysmograph, as described above. Thus, the red and IR ratios can be denoted as NP_{RD} and NP_{IR} respectively, where NP stands for "normalized plethysmograph." In pulse oximetry, oxygen saturation is calculated from the ratio NP_{RD}/NP_{IR}.

SUMMARY OF THE INVENTION

Oxygen saturation is a very useful physiological parameter for indicating the cardiovascular status of a patient, but allows healthcare providers only a few minutes warning that a patient is potentially having a medical crisis. A wellness indicator advantageously monitors changes in a patient's "tissue profile" so as to provide an advance warning of a deteriorating medical condition. This tissue profile is provided by a multiple wavelength sensor and a noninvasive multi-parameter patient monitor, which make blood absorption measurements at more than a red wavelength and an IR wavelength of conventional pulse oximetry. In one embodiment, described below, blood absorption measurements are made at eight wavelengths. Advantageously, this rich wavelength data characterizes a tissue site over a wavelength spectrum.

FIG. **2** illustrates an example of a tissue profile. In this example, the sensor emits eight wavelengths (610, 620, 630, 655, 700, 720, 800 and 905 nm). A tissue profile graph **200** has a NP ratio axis **201** and a wavelength axis **202**, where the NP ratios are of the form $NP_{\lambda 1}/NP_{\lambda 2}$. This is a generalization to multiple wavelengths of the ratio NP_{RD}/NP_{IR} described above for two (red and IR) wavelengths. In order to provide a common scale for these NP ratios, the ratios are calculated with respect to a reference wavelength, λr, which may be any of the available wavelengths. Thus, the plotted NP ratios **210** are denoted $NP_{\lambda n}/NP_{\lambda r}$. Note that the NP ratio at the reference wavelength is $NP_{\lambda r}/NP_{\lambda r}=1$, which is 700 nm in this example. In this example, a tissue profile **210** is plotted for Sp02=97%.

Not surprisingly, the tissue profile **210** has the same general shape as the absorption curves **110**, **120** of FIG. **1**. In particular, the AC component of the detector signal relative to the DC component (NP) for a specific wavelength is proportional to the light absorption at that wavelength. Thus, the NP ratio magnitudes and hence the points along a tissue profile curve are proportional to absorption. Assuming negligible abnormal Hb species, if SpO_2 is close to 100%, most of the absorption is due to HbO_2 and, accordingly, the tissue profile is shaped closely to the HbO_2 absorption curve. As SpO_2 decreases from 100%, the tissue profile shape is increasing influenced by the shape of the Hb absorption curve.

In one embodiment, the tissue profile **210** consists solely of the measured NP ratios at the sensor wavelengths, i.e. a finite set of discrete values. In another embodiment, the tissue profile **210** consists of the measured NP ratios and defined NP ratio values between the sensor wavelengths, which are based upon tissue absorption characteristics. That is, the tissue profile **210** is a curve defined over a continuous range of wavelengths, including the sensor wavelengths. Although described above with respect to NP ratios derived from the AC component of the detector signal, a DC tissue profile may also be defined and applied to patient monitoring, as described below.

A tissue profile or tissue characterization is described in U.S. patent application Ser. No. 11/367,034, filed Mar. 1, 2006 entitled Physiological Parameter Confidence Measure; a multiple wavelength sensor is disclosed in U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 entitled Multiple Wavelength Sensor Emitters; and a multi-parameter patient monitor is disclosed in U.S. patent application Ser. No. 11/367,033, filed Mar. 1, 2006 entitled Noninvasive Multi-Parameter Patient Monitor, all of the aforementioned applications are assigned to Masimo Laboratories, Inc., Irvine, Calif. and all are incorporated by reference herein.

One aspect of a tissue profile wellness monitor comprises generating a tissue profile, predetermining rules and applying the rules to the tissue profile. The tissue profile is responsive to absorption of emitted wavelengths of optical radiation by pulsatile blood flowing within a tissue site. The rules are used to evaluate at least a portion of the tissue profile. A patient condition is indicated according to the applied rules.

Another aspect of a tissue profile wellness monitor comprises measuring a normalized plethysmograph (NP) to generate a tissue profile, testing the tissue profile and outputting the test results. The NP is measured at each of multiple wavelengths of optical radiation, and the NP is responsive to attenuation of the optical radiation by constituents of pulsatile blood flowing within a tissue site illuminated by the optical radiation. The tissue profile is tested against predetermined rules. The test results are output as at least one of a display, alarm, diagnostic and control.

A further aspect of a tissue profile wellness monitor comprises measuring a physiological parameter, generating a tissue profile, defining limits and indicating when the tissue profile exceeds the defined limits. The physiological parameter is responsive to multiple wavelengths of optical radiation after attenuation by constituents of pulsatile blood flowing within a tissue site. The tissue profile is responsive to the physiological parameter. The limits are defined for at least a portion of the tissue profile.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a graph of oxyhemoglobin and reduced hemoglobin light absorption versus wavelength across portions of the red and IR spectrum;

FIG. **2** is a graph of normalized plethysmograph (NP) ratios versus wavelength illustrating a tissue profile for 97% oxygen saturation;

FIG. **3** is a general block diagram of a patient monitoring system embodiment that implements a tissue profile wellness monitor;

FIG. **4** is a graph of tissue profiles for high saturation, low saturation, high carboxyhemoglobin (HbCO) and high methemoglobin (MetHb);

FIG. **5** is a graph illustrating tissue profile changes indicative of patient wellness; and

FIG. **6** is a block diagram of a tissue profile wellness monitor embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **3** illustrates a patient monitoring system **300**, which generates NP ratios and blood parameter measurements, such SpO_2, HbCO and HbMet, accordingly. The patient monitoring system is advantageously adapted as a tissue profile wellness monitor, as described below. The patient monitoring system **300** has a patient monitor **302** and a sensor **306**. The sensor **306** attaches to a tissue site **320** and includes a plurality of emitters **322** capable of irradiating the tissue site **320** with differing wavelengths of light, perhaps including the red and infrared wavelengths utilized in pulse oximeters. The sensor **306** also includes one or more detectors **324** capable of detecting the light after attenuation by the tissue site **320**. A multiple wavelength sensor is disclosed in U.S. patent application Ser. No. 11,367,013, filed on Mar. 1, 2006, titled Multiple Wavelength Sensor Emitters, cited above. Multiple wavelength sensors, such as Rainbow™-brand adhesive and reusable sensors are available from Masimo Corporation, Irvine, Calif.

As shown in FIG. **3**, the patient monitor **302**, communicates with the sensor **306** to receive one or more intensity signals indicative of one or more physiological parameters. Drivers **310** convert digital control signals into analog drive signals capable of driving the sensor emitters **322**. A front-end **312** converts composite analog intensity signal(s) from light sensitive detector(s) **324** into digital data **342** input to the DSP **340**. The DSP **340** may comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In an embodiment, the DSP **340** executes the processors **610**, **620**, **630** (FIG. **6**), described below.

The instrument manager **360** may comprise one or more microcontrollers providing system management, such as monitoring the activity of the DSP **340**. The instrument manager **360** also has an input/output (I/O) port **368** that provides a user and/or device interface for communicating with the monitor **302**. In an embodiment, the I/O port **368** provides threshold settings via a user keypad, network, computer or similar device, as described below.

Also shown in FIG. **3** are one or more user I/O devices **380** including displays **382**, audible indicators **384** and user inputs **388**. The displays **382** are capable of displaying indicia representative of calculated physiological parameters such as one or more of a pulse rate (PR), plethysmograph (pleth), perfusion index (PI), signal quality and values of blood constituents in body tissue, including for example, oxygen saturation (SpO_2), carboxyhemoglobin (HbCO) and methemoglobin (HbMet). The monitor **302** may also be capable of storing or displaying historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The monitor **302** may also provide a trigger for the audible indictors **384**, which operate beeps, tones and alarms, for example. Displays **382** include for example readouts, colored lights or graphics generated by LEDs, LCDs or CRTs to name a few. Audible indicators **384** include speakers or other audio transducers. User input devices **388** may include, for example, keypads, touch screens, pointing devices, voice recognition devices, or the like.

FIG. **4** illustrates tissue profile curves **400**, which are responsive to Hb constituents. In this example, the sensor emits eight wavelengths (610, 620, 630, 660, 700, 720, 805, 905 nm), which are normalized at 700 nm. Shown is a high

saturation profile curve **420**, e.g. Sp02≈100% (◇); a low saturation profile curve **440**, e.g. Sp02=70% (□); a high HbCO profile curve **460**, e.g. HbCO=30% (A); and a high HbMet profile curve **480**, e.g. HbMet=6% (x). The profile curves **420-480** each has a head portion **401** at wavelengths less than 700 nm and a corresponding tail portion **402** at wavelengths of greater than 700 nm. As shown in FIG. **4**, a tissue profile head portion **401** has higher values when HbCO (Δ) or HbMet (x) has a higher percentage value. The head portion **401** has lower values when HbCO or HbMet has a lower percentage value. Also, both the head portion **401** and the tail portion **402** have higher values when Sp02 is a high percentage (◇) and lower values when Sp02 is a low percentage (□).

FIG. **5** illustrates an example tissue profile **500** utilized as a wellness indicator. As described with respect to FIG. **4** above, the position or shape of the tissue profile or changes in the position or shape of the tissue profile provide an indication of patient wellness. In particular, position, shape or relative movements of the curve "head" **510** or the curve "tail" **520** or both indicate potentially detrimental values or changes in values of hemoglobin constituents. For example, a drop in the tissue profile head **510** or tail **520** below a predefined boundary **530**, **540** may indicate reduced oxygen saturation. As another example, a rise in the tissue profile head **510** above a predefined boundary **550** may indicate increased concentrations of abnormal hemoglobin species, such as carboxyhemoglobin (HbCO) and methemoglobin (HbMet). Further, relative movements **570**, **580** of the tissue profile **500** faster than a predefined rate may indicate potentially serious trends in the concentrations of normal or abnormal hemoglobin species.

FIG. **6** illustrates a tissue profile wellness monitor **600** having a NP processor **610**, a tissue profile processor **620** and an output processor **630**. In an embodiment, these processors **610-630** execute in the DSP **340** (FIG. **3**) to monitor tissue profile changes. The NP processor **610** has digitized sensor signal input **601** from one or more sensor channels, such as described with respect to FIG. **3**, above, and generates normalized plethysmograph (NP) calculations **612** as described with respect to FIG. **1**, above.

As shown in FIG. **6**, the tissue profile processor **620** is configured to compare tissue profile changes **612** with respect to predetermined rules **603** and communicate the test results **622** to the output processor **630**. As an example, the tissue profile processor **620** may communicate to the output processor **630** when a tissue profile portion changes faster than a predetermined rate.

Also shown in FIG. **6**, the output processor **630** inputs the tissue profile processor results **622** and generates outputs **602** based upon predetermined output definitions **605**. For example, if a test profile result is "true", it might trigger an audible alarm. Rules and corresponding outputs are described in further detail with respect to TABLE 1, below.

In an embodiment, the tissue profile wellness monitor **600** provides outputs **602** according to TABLE 1, below. The terms listed in TABLE 1 are described with respect to FIG. **6**, above. Various other indicators, alarms, controls and diagnostics in response to various combinations of rules and output definitions can be substituted for, or added to, the rule-based outputs illustrated in TABLE 1.

In an embodiment, the tissue profile wellness monitor **600** grades a patient with respect to wellness utilizing green, yellow and red indicators. For example, a green panel light signals that the tissue profile is indicative of normal blood hemoglobin. A yellow panel light signals that changes in the tissue profile shape or position are indicative of potentially problematic changes in blood hemoglobin. A red panel light signals that the tissue profile is indicative of blood hemoglobin outside of normal ranges.

TABLE 1

Tissue Profile Rules and Outputs

TISSUE PROFILE RULES	OUTPUTS
If all portions of tissue profile are within boundaries and relatively unchanging over time	Then illuminate green indicator.
If tail drops faster than tail trend limit; or head rises faster than head trend limit	Then illuminate yellow indicator
If tail or head are outside of boundaries	Then illuminate red indicator

A tissue profile wellness monitor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. A physiological monitoring method comprising:
emitting a plurality of wavelengths of light into a tissue site of a patient including pulsating blood;
detecting the light after attenuation by the tissue site;
at each of the plurality of wavelengths, generating a signal responsive to the detected light;
normalizing each of the plurality of generated signals;
generating a tissue profile in response to the plurality of normalized signals using a processor; and
analyzing the tissue profile using the processor to determine patient wellness.

2. The physiological monitoring method of claim **1**, wherein analyzing comprises:
determining whether the tissue profile is within predetermined boundaries, the predetermined boundaries indicative of patient wellness.

3. The physiological monitoring method of claim **2**, wherein patient wellness is determined based at least in part on the shape of the tissue profile.

4. The physiological monitoring method of claim **2**, wherein determining comprises:
dividing the tissue profile into a head portion and a tail portion; and
evaluating the head portion separately from the tail portion, wherein the head portion is compared to predetermined head boundaries, and the tail portion is compared to predetermined tail boundaries.

5. The physiological monitoring method of claim **1**, wherein measuring a physiological parameter and generating a tissue profile are each performed repeatedly.

6. The physiological monitoring method of claim **5**, wherein analyzing comprises, for each generated tissue profile:
dividing the tissue profile into a head portion and a tail portion;
comparing the head portion to a head boundary; and
comparing the tail portion to a tail boundary.

7. The physiological monitoring method of claim **6**, wherein analyzing further comprises, for each generated tissue profile:
comparing a rate of change of the head portion to a head trend limit; and
comparing a rate of change of the tail portion to a tail trend limit.

8. The physiological monitoring method of claim 7, further comprising:

outputting a first signal indicative of patient normalcy when the head portion is within the head boundary and changing more slowly than the head trend limit and the tail portion is within the tail boundary and changing more slowly than the tail trend limit;

outputting a second signal indicative of caution when at least one of the head portion is changing more quickly than the head trend limit and the tail portion is changing more quickly than the tail trend limit; and

outputting a third signal indicative of high alert when at least one of the head portion is outside the head boundary and the tail portion is outside the tail boundary.

9. A patient monitoring device for generating and analyzing a tissue profile, the device comprising:

a sensor comprising a light source that emits a plurality of wavelengths of light into a tissue site of a patient and a detector that detects the emitted light after attenuation by the tissue site, wherein the sensor is configured to generate, at each of the plurality of wavelengths, a signal responsive to the detected light; and

a patient monitor in communication with the sensor, the patient monitor configured to:

normalize each of the plurality of generated signals;

generate a tissue profile responsive to at least some of the plurality of normalized signals using a processor; and

analyze the tissue profile using the processor to determine patient wellness.

10. The patient monitoring device of claim 9, wherein the patient wellness is determined based at least in part on the shape of the tissue profile.

11. The patient monitoring device of claim 10, wherein patient wellness is indicated by at least one of a display, an alarm, diagnostic and a control.

12. The patient monitoring device of claim 9, wherein, in order to generate a tissue profile, the patient monitor is further configured to:

measure values of at least some of the plurality of signals associated with respective emitted wavelengths;

define additional values corresponding to at least a portion of a wavelength spectrum between the respective emitted wavelengths associated with the at least some of the plurality of signals based on characteristics of the tissue site; and

normalize the measured values and additional values with respect to a reference wavelength.

13. The patient monitoring device of claim 12, wherein, in order to analyze the tissue profile shape, the patient monitor is further configured to:

set a limit corresponding to the tissue profile; and

specify an output corresponding to a comparison of the tissue profile to the set limit.

14. The patient monitoring device of claim 13, wherein, in order to set a limit, the patient monitor is further configured to:

define at least one of a boundary and a maximum rate of change for at least a portion of the tissue profile.

15. The patient monitoring device of claim 14, wherein the patient monitor is further configured to:

output a first signal indicative of patient normalcy when the tissue profile is within the boundary and the tissue profile rate of change is less than the maximum rate of change; and

output a second signal indicative of alert when at least one of the tissue profile is outside of the boundary and the tissue profile rate of change is greater than the maximum rate of change.

16. A method of providing advance warning of deteriorating patient wellness, the method comprising:

transmitting multiple wavelengths of light through a tissue site of a patient;

measuring an attenuation by the tissue site of each of the wavelengths of transmitted light;

determining, for each measured attenuation of each wavelength of transmitted light, a normalized plethysmograph (NP);

selecting a reference wavelength from the multiple transmitted wavelengths;

calculating a wellness indicator by normalizing the NP of each wavelength by the NP of the reference wavelength; and

comparing the calculated wellness indicator to predetermined limits, wherein the wellness indicator exceeding the predetermined limits indicates advance warning of deteriorating patient wellness.

17. The method of claim 16, wherein the reference wavelength divides the wellness indicator into a first portion and a second portion, and wherein the first portion is compared to a first portion predetermined limit, and the second portion is compared to a second portion predetermined limit.

18. The method of claim 16, further comprising:

defining continuous normalized NP values corresponding to at least a portion of a wavelength spectrum between the two or more of the multiple transmitted wavelengths based at least in part on characteristics of the tissue site; and

calculating a continuous wellness indicator by combining the normalized NP values at each transmitted wavelength with the defined continuous normalized NP values.

* * * * *